

## REMARKS

**Office action summary.** The Examiner states that “While applicant has argued claim 1 and why such is not anticipated or obvious, there are no arguments or discussion of independent claims 9 and 11 and their dependents, such claims not using the photoresist as the microneedle structure.”

Applicants in fact argued the non-obviousness of claim 11 in the prior response, but by mistake applicants’ counsel omitted to state that the same arguments apply to claim 9. Applicants’ counsel apologizes for this oversight. The present additional response is self-contained as regards the prior art rejections of claims 1, 9, and 11; it therefore includes the arguments made in the prior response as well as additional arguments.

**Anticipation rejections.** Newly amended claim 1 recites that the microneedles are comprised of the photoresist, avoiding the purported ambiguity noted by the Examiner whereby the claim “does not positively recite that the photoresist material is in fact the microneedle structure itself.” (10/1/07 Action at 2). At a minimum this limitation overcomes the anticipation rejection, since the fabrication of microneedle arrays comprised of photoresist is not disclosed by Prausnitz.

The passage spanning columns 21 and 22 which the Examiner cites in relation to anticipation discloses merely a conventional use of photoresist to provide a mask. It states that “[a]rrays of cylindrical holes are then photolithographically defined through the epoxy layer,” a conventional use of photoresist. Prausnitz does not fabrication of microneedle arrays comprised of photoresist.

Claim 2 is not anticipated, at a minimum, because it depends on claim 1 and claim 1 is not anticipated. The other independent claims, 9 and 11, are not rejected as anticipated.

**Obviousness rejections.** The Examiner has failed to meet the requirements for a *prima facie* case of obviousness over the Prausnitz reference.

The use of photoresist to make the actual microneedles is nonobvious as shown by the fact that Prausnitz uses photoresist for other purposes but not for actual microneedles. The inventors recognized that photoresist, which is an unusually malleable and flexible way to make microstructures of different kinds, is suitable for arrays of microneedles. The prior art generally taught the use of silicon, metals, and the like to make microneedle arrays because of the perceived need for stiffness, or if polymeric materials were used one would deposit metals onto

them to achieve stiffness, as in Prausnitz. The applicants' use of materials perceived as "softer," such as photoresist, to make microneedles arises from an understanding of the true needs of this mode of drug delivery.

Claim 11 expressly recites that a "patterned photoresist material/substrate" is the master used to make a replica mold – as the claim states, the moldable material is applied onto the "patterned photoresist material/substrate" itself, *not* onto something else derived from that object. While the Examiner has stated generally that claim 11 is obvious, there is no specific discussion in the Action of why the prior art teaches, suggests, or would lead a person of skill in the art to make a master for a replica mold out of photoresist. Again, the prior art tended to view such molds as having to be made of metal or silicon or other stiffer materials which the present inventors found not to be necessary.

Claim 9 expressly recites "coating said patterned photoresist material with a layer of moldable material that takes the negative form of said plurality of microstructures, and allowing said moldable material to harden using a soft lithography procedure, then separating said hardened moldable material from both said patterned photoresist material and said substrate material." Thus, like claim 11, but in somewhat different words, claim 9 requires that the patterned photoresist material be the master used to make a replica mold. For the same reasons stated above in connection with claim 11, claim 9 is not obvious over Prausnitz.

The Examiner has further stated that Prausnitz "discloses embossing as a way to pattern the molded material against the mold. Soft lithography involves such a step." (Action mailed 10/1/07 at 5.) This is not a correct understanding of soft lithography; while there is a brief mention of embossing on p. 175 of the Xia-Whitesides paper, the soft lithography techniques discussed in the bulk of that paper do not involve embossing. In addition, embossing is described by Prausnitz as a "standard mold transfer technique" (col. 19, line 6), whereas soft lithography is employed in claims 9 and 11 in order to allow moldable materials to harden, not as a complete "mold transfer technique."

Claims dependent on claims 9 and 11 are not obvious, at a minimum, because claims 9 and 11 are not obvious. Furthermore, the Examiner's discussion of the dependent claims employs such phrases as "this is rather conventional in the medical art," which are not a proper substitute for evidence of the prior art.

In sum, the applicants have made a patentable advance over the prior art which leads to more economical and flexible ways of making microneedle arrays. The obviousness rejection should therefore be withdrawn.

**Conclusion.** If the Examiner has any questions about this response it is respectfully requested that he telephone the undersigned attorney.

Respectfully submitted,

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